

K071051

NOV - 2 2007

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**REGULATORY AUTHORITY**

Safe Medical Devices Act of 1990, 21 CFR 807.92

**COMPANY NAME/CONTACT**

Heather MacFalls  
Reliant Technologies, Inc.  
464 Ellis St.  
Mountain View, CA 94043  
650 605-2257  
650 605-2057 fax  
[hmacfalls@fraxel.com](mailto:hmacfalls@fraxel.com)

**NAME OF DEVICE**

Trade Name:	<u>Fraxel III SR Laser System (Fraxel re:pair™) and Accessories</u>
Common Name:	Laser Surgical Instrument
Regulation Number	878.4810
Product code:	GEX
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

**LEGALLY MARKETED PREDICATE DEVICES**

Name: Fraxel SR Laser System and Accessories  
510(k) #: K053047, K050841, K042319, K040617 and K031795

Name: Fraxel II SR Laser System and Accessories  
510(k) #: K062303

Name: Fraxel III SR Laser System and Accessories  
510(k) #: K063038

Name: Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories  
510(k) #: K022060, K030147

**DEVICE DESCRIPTION**

The Fraxel III SR Laser System consists of a laser source which delivers a pattern of thermal energy to the epidermis and dermis using scanning and focusing optics. Device accessories include interchangeable treatment tips.

K071051

## **INDICATION FOR USE STATEMENT**

The Fraxel III SR (Fraxel re:pair™) Laser System is intended for use in:

Dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue.

Treatment of wrinkles, rhytides, furrows, fine lines, texture irregularities, pigmented lesions and vascular dyschromia.

## **SUBSTANTIAL EQUIVALENCE COMPARISON**

### **Indications for Use**

Substantial equivalence for the Fraxel III SR (Fraxel re:pair) Laser System and Accessories is supported by the predicate devices listed in this submission, which have identical or similar indication statements.

### **Clinical Performance Data**

Non-Significant Risk and Investigational Device Exemption studies support the clinical performance of the Fraxel III SR (Fraxel re:pair) Laser System. Sufficient clinical data supported the determination of safety and effectiveness for the Fraxel III SR (Fraxel re:pair) Laser System and Accessories. The device performed as clinically intended with no new issues of safety and effectiveness introduced.

### **Technological Characteristics**

Key technological characteristics of the Fraxel III SR (Fraxel re:pair) Laser System, such as energy type and operating principle, are equivalent to the Fraxel SR Laser System as described in submissions K053047, K050841, K042319, K040617 and K031795, to the Fraxel II SR Laser System as described in K062303 and to the Lumenis Ultrapulse Encore Laser System as described in K020660 and K030147.

## **CONCLUSION**

Based on the design, materials, function, intended use and clinical evaluation, the Fraxel III (Fraxel re:pair) Laser System and Accessories is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. Safety and effectiveness are reasonably assured, justifying 510(k) clearance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV - 2 2007

Reliant Technologies, Inc.  
% Ms. Heather MacFalls  
Clinical and Regulatory Affairs  
464 Ellis Street  
Mountain View, California 94043

Re: K071051

Trade/Device Name: Fraxel III SR Laser System (Fraxel re:pair™) and Accessories  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: August 1, 2007  
Received: August 7, 2007

Dear Ms. MacFalls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

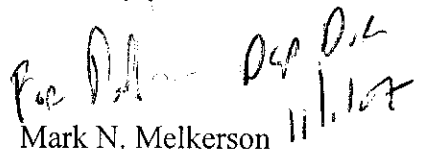
Page 2 - Ms. Heather MacFalls

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
Mark N. Melkerson  
Director  
Division of General, Restorative,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K071051

Device Name: Fraxel III SR Laser System (Fraxel re:pair™) and Accessories  
Indications For Use:

"The Fraxel III SR Laser System and accessories is intended for use in:

Dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue.

Treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions and vascular dyschromia."

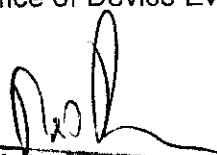
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

Page 1 of 1

510(k) Number K071051